K0 11941

AUG 2 2 2001

EXHIBIT # 12

510(k) Summary

Kendall Excilon® A.M.D. Antimicrobial Sponges

In accordance with section 513(I) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

The Kendall Company / Division of Tyco Healthcare
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: June 20, 2001

1. Contact Person

Michael P. Spears
Regulatory Affairs Specialist
Phone - (508) 261-8155
Fax -(508) 261-8461

2. Name of Medical Device

Proprietary Name:	Excilon® A.M.D. Antimicrobial Sponges
Common Name:	wound dressing
Classification Name:	dressing

3. Identification of Legally Marketed Device

The proposed Kendall Excilon® A.M.D. Antimicrobial Sponge is substantially equivalent in intended use, function and composition to the Kendall Kerlix AMD Antimicrobial Gauze, 510(k) No. K990530 and the Acticoat® Primary Antimicrobial Dressing, 510(k) No. K992221.

4. Device Description

The proposed Kendall Excilon® A.M.D. Antimicrobial Sponge is a sterile, single use wound dressing consisting of nonwoven material treated with Cosmocil®CQ. Polyhexamethylene Biguanide Hydrochloride (PHMB) is the active ingredient in Cosmocil ®CQ. The sponges have a slit cut in them from the center of one side up through the midpoint wher a T-cut is formed. The dressing is packaged in a paper paper pouch and will be available in 2" x 2" and 4" x 4" sponge form.

K011941

5. Device Intended Use

Excilon® A.M.D. Antimicrobial Sponges are intended for use as primary dressings for IV sites, Tracheostomy tube sites, chest tube sites, catheter sites and drain sites. The antimicrobial activity of the PHMB in Excilon® A.M.D. helps to resist bacterial colonization of the dressing and inhibit bacterial penetration through the dressing. The barrier function of the dressing may help reduce infections in partial and full thickness wounds.

6. Product Comparison

The Kendall Excilon® A.M.D. Antimicrobial Sponge is equivalent to the referenced predicate devices in that they are intended to be used as wound dressings. They each contain an ingredient that enhances the bacterial barrier function of the dressings and each has a broad spectrum of antimicrobial activity.

7. Nonclinical Testing

Biocompatibility testing of the proposed device has demonstrated that it meets the requirements of guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2001

Mr. Michael P. Spears
Regulatory Affairs Specialist
The Kendall Company
Division of Tyco Healthcare Group
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K011941
Trade/Device Name: Excilon A.M.D. Antimicrobial Sponge
Regulatory Class: Unclassified
Product Code: EFQ
Dated: June 20, 2001
Received: June 21, 2001

Dear Mr. Spears:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011941

Device Name: Excilon A.M.D. Antimicrobial Sponge

Indications For Use:

Primary dressing for IV sites, tracheostomy tube sites, chest tube sites, catheter and drain sites.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011941

Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)